REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration, because the amendments amplify issues previously discussed throughout prosecution; does not present any additional claims; and places the application in better form for an appeal should an appeal be necessary. The Amendment is necessary and was not earlier presented because it is made in response to arguments raised in the final rejection. Entry of the Amendment, reexamination and further and favorable consideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

As correctly stated in the Office Action, Claims 55-99 are pending in the present application. Claims 55-58, 61-79, 82, 85-94, and 97 stand rejected. Claims 59, 60, 80, 81, 83, 84, 95, 96, 98, and 99 stand withdrawn from consideration.

By the present amendment, Claim 55 has been amended to recite a "homogeneous" carrier system. Support for this amendment can be found, at least, on page 3, line 27 to page 4, line 2. Claim 86 has been amended to more precisely define the invention. Support for the amendment to Claim 86 can be found, at least, in Claim 86, as originally filed. No new matter has been added.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 86 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner argues that the term "low" is not defined by the claim, nor by the specification. Without conceding the grounds of this rejection and solely in an effort to expedite prosecution, this language has been deleted from Claim 86, thereby mooting the rejection. Withdrawal of this rejection is thus respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 55-58, 61-79, 82, 85-94, and 97 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Yamada *et al.* (U.S. Patent 5,362,497) in view of Wang *et al.* (U.S. Patent No. 4,299,828) and Cooper *et al.* (U.S. Patent No. 4,552,872). In the previous Office Action mailed April 17, 2001, the Examiner argued that Yamada *et al.* disclose a transdermal therapeutic composition comprising a pharmaceutical active ingredient, a water-soluble absorption enhancer, a fat soluble absorption enhancer comprising fatty alcohol, and a lower alchol ester of aliphatic carboxylic acid. The Examiner admitted that Yamada *et al.* do not expressly teach the particular formulation of the invention "which has corticosteroid as the active ingredient, and comprising unsaturated alcohols, lower alcohol ester of fatty acid, wax, and plasticizing oil with the particular percentage, or the particular form, stick, or the method of using the same." [See Official Action mailed April 17, 2001, pages 3-4]. However, the Examiner suggested that Cooper *et al.* disclose unsaturated alcohols are particularly useful in topical corticosteroid compositions and the inclusion of wax for stiffness. The Examiner further believes that

Wang *et al.* disclose a corticosteroid stick formulation with wax. Thus, the Examiner surmised that one of "ordinary skill in the art would be motivated to modify the composition of Yamada to make a corticosteroid topical composition employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the particular amounts claimed herein because both are known to be useful to enhance the absorption of active ingredients...The employment of wax and plasticizer to render the final product certain properties is seen to been within the skill of artisan." [See Official Action mailed April 17, 2001, pages 4-5]. This rejection, to the extent that it applies to the claims as amended, is respectfully traversed.

In order to establish *prima facie* obviousness under 35 U.S.C. § 103, the cited reference or combination of references must teach or suggest every element of the claims. Moreover, there must be motivation, outside of Applicants' disclosure, to modify or combine the cited references. See M.P.E.P. 2143 *et seq.*

Claim 55, as amended, explicitly recites "a solid, dermatological composition comprising a biologically active agent dissolved in a **homogeneous** carrier system." Applicants maintain their position that Yamada *et al.* is *irrelevant* to the presently claimed invention. Applicants' invention is intended to solve the problem presented in the "Background of the Invention" section of the present application on page 1, line 13, to page 3, line 2. Namely, the presently claimed invention seeks to attain a satisfactory solid composition, preferably in the form of a stick. Applicants acknowledge that Yamada *et al.* disclose a transdermal composition comprising an active ingredient, e.g., a corticosteroid, a water-soluble absorption enhancer, e.g., propylene alcohol, a fat-soluble enhancer, e.g.,

oleyl alcohol, and a lower alcohol, e.g., myristic acid. However, Applicants respectfully point out that the Examiner has neglected to recite a prominent feature of Yamada *et al.*: the benefit of separating the water-soluble and fat-soluble enhancers via the use of a "superabsorbing" polymer (column 2, lines 25-35). Further, Yamada *et al.* disclose a two or higher phase system where the water-soluble enhancer is absorbed in a polymer separated from the fat-soluble enhancer. The superabsorbing resin is a requisite part of the Yamada *et al.* invention. The presently claimed invention relates to a *single* phase mixture of enhancers, an active ingredient and a defined lipid composition as explicitly recited in the claims. The Yamada *et al.* publication, in seeking to keep the enhancers separated from each other, thus *teaches away* from the presently claimed invention. Formulations according to the presently claimed invention must not contain water while the Yamada *et al.* teach the use of water and emulsifiers to create a multiphase system. Applicants further submit that the invention of Yamada *et al.* is intended for transdermal delivery of a therapeutic composition in order to produce the intended *systemic* effect (column 1, lines 19-23), while Applicants' invention is directed toward the *local delivery* of the therapeutic ingredient *to the skin*.

Applicants also maintain their earlier argument that Cooper *et al.* also teach away from the presently claimed invention. The Examiner's attention is directed to column 10, lines 35-54, wherein Cooper *et al.* specifically state that the use of hydrocarbons should be avoided or limited to not more than 10%, preferably not more than 5%. Applicants have discovered satisfactory delivery of the active ingredient in a composition that contradicts the teachings of Cooper *et al.* Cooper *et al.* also state that fatty alcohols should be avoided due

to lowered absorption of the active ingredient and that the use of oils should preferably be limited to less than 0.5% (column 10, line 55, to column 11, lines 17), which is also in direct contrast to the claimed invention.

Applicants submit that, even when considered together, the cited publications do not contain all the elements of the presently claimed invention. Further, Applicants have clearly demonstrated that both Yamada *et al.* and Cooper *et al.* teach away from, rather than suggest, the presently claimed invention. Applicants strongly disagree that the combination of the Yamada *et al.* and Cooper *et al.* publications (in further combination with Wang *et al.*) would have thus motivated one skilled in the art to arrive at the present invention. Accordingly, Applicants submit that the presently claimed invention cannot be *prima facie* obvious over Yamada *et al.* in view of Wang *et al.* and Cooper *et al.* Accordingly, withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: December 13, 2001

Attachment to REPLY & AMENDMENT dated December 13, 2001

Marked-up Claims 55 and 86

55. (Amended) A solid, dermatological composition comprising a biologically active agent dissolved in a homogeneous carrier system, wherein the carrier system includes

a) a solvent for said active agent, comprising 20 to 85% by weight of an unsaturated fatty acid alcohol in combination with an alkylene glycol, said fatty acid alcohol being selected from oleyl alcohol, ricinolyl alcohol, linolyl alcohol and/or linolenyl alcohol, and said alkylene glycol being selected from propylene glycol and/or dipropylene glycol, the alkylene glycol being present in an amount of more than 12% by weight to provide for mutual dissolution of said active agent;

b) a viscosity enhancing agent for imparting a solid consistency to the composition which comprises 15 to 55% by weight of a waxy substance; and

c) a plasticizing agent which comprises 2 to 30% by weight of a plasticizing oil;

all percentages being based on the total weight of the carrier system.

86. (Twice Amended) A composition as claimed in Claim 55, wherein the plasticizing oil is selected from [low molecular weight] branched chain aliphatic acids and alcohols which reduce the viscosity of the carrier system.